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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,596	05/11/2005	J Richard Gyory	TP15023USPCT	7156
27777	7590	10/04/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER LU, JIPING	
			ART UNIT	PAPER NUMBER
			3749	
			MAIL DATE	DELIVERY MODE
			10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,596

Applicant(s)

GYORY ET AL.

Examiner

Jiping Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/28/07</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a freeze-drying microscope stage.

Group II, claim(s) 41-45, drawn to a method of screening an array of samples for evaluating suitability for freeze-drying.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventive concept for Group I claim is a freeze-drying microscope stage comprising (a) at least one lyophilization plate comprising a plurality of stacked optically clear-layers; (b) a plurality of chambers in said at least one lyophilization plate; (c) at least one pressure and temperature controlled chamber having optically clear windows; and (d) heating, cooling, and pressure controls connected to the freeze-drying microscope stage. The inventive concept for Group II claim is a method of screening an array of samples for evaluating suitability for freeze-drying comprising (a) preparing at least 24 samples to form the array of samples, wherein at least two samples comprise a lyophilizable solvent; (b) freezing a plurality of samples in the array of samples; (c) subjecting the plurality of samples to a freeze-thaw cycle by thawing and refreezing; (d) subjecting the plurality of samples to a

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pressure in the range defined by at least 50 micrometers of Hg to no more than 760 millimeters of Hg; and (e) examining, visually, at least one sample in the plurality of samples to determine if the temperature has exceeded the glass transition temperature for the sample.

2. During a telephone conversation with Attorney Paul Burgess on 9/19/07, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 41-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey (U. S. Pat. 4,521,975) in view of Taggart (U. S. Pat. 3,451,189) or Jellicich (U. S. Pat. 3,397,462).

Bailey shows a freeze-drying microscope stage comprising at least one lyophilization plate 30 comprising a plurality of stacked layers 14, 28, a plurality of chambers 12 in said at least one lyophilization plate, at least one pressure and temperature controlled chamber 18 and heating 38, cooling 42 and pressure 40 controls connected to the freeze-drying microscope which are arranged same as claimed. However Bailey does not show the optically clear-layers and optically clear windows. Taggart teaches a freeze-drying apparatus with viewing windows 21. Jellicich teaches a lyophilization apparatus with transparent peep-hole 12 for checking the contents of the cell-loader when closed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the freeze-drying microscope stage of Bailey to include a optically clear window as taught by Taggart or Jellicich in order to facilitate viewing the contents inside the chamber. With regard to the claimed optically clear-layer, it would have been an obvious matter of design choice to design the lyophilization plate of Bailey with any desired material in order to obtain the optimum and predictable result since applicant has not disclosed that the claimed optical clear layers solve any stated problem in a new or unexpected way or is for any particular purpose which is unobvious to one of ordinary skill in the art and it appears that the claimed feature does not distinguish the invention over similar features in the prior art since, the free-drying microscope stage of Bailey will perform the invention as claimed by the applicant with the lyophilization plate having any kind of the layers. As for the limitations, "a freeze-drying microscope stage for screening an array.... At least 24 samples" in lines 1-3 of claim 1, and the limitations in claims 2-8, they are viewed as functional

or intended use limitations. As MPEP 2114 states, “[a] claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim”. In this case, the limitations above do not add any structural limitations to the claim and the freeze-drying microscope stage of Bailey as modified by Taggart or Jellicich discloses all the structural limitations.

6. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey (U. S. Pat. 4,521,975) in view of Taggart (U. S. Pat. 3,451,189) or Jellicich (U. S. Pat. 3,397,462) as applied to claim 6 above, and further in view of Suzuki et al. (U. S. Pat. 4,859,360).

The freeze-drying microscope stage of Bailey as modified by Taggart or Jellicich as above includes all that is recited in claims 9-16 except for each sample comprising a formulation for determining a glass transition temperature. Suzuki et al teaches a concept of using formulation for indicating the glass transition temperature same as claimed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the freeze-drying microscope stage of Bailey to provide each sample with temperature indication formulation of Suzuki et al. in order to monitor the glass transition temperature. As for the limitations, “which enable.... fraction” in lines 3-5 of claim 9, and the limitations in claims 10-13, “to determine.... Formulation” in last line of claims 14-16, they are viewed as functional or intended use limitations. As MPEP 2114 states, “[a] claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim”. In this case, the limitations above do not add any

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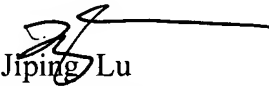
structural limitations to the claim and the freeze-drying microscope stage of Bailey as modified by Taggart or Jellicich and Suzuki et al. discloses all the structural limitations.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jiping Lu whose telephone number is 571 272 4878. The examiner can normally be reached on Monday-Friday, 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, STEVEN B. MCALLISTER can be reached on 571 272-6785. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jiping Lu
Primary Examiner
Art Unit 3749

J. L.